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10/705,402	11/10/2003	Satoshi Mizutani	20050/0200486-US0	4520
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DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			REICHLE, KARIN M.	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/705,402

Applicant(s)

MIZUTANI ET AL.

Examiner

Karin M. Reichle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2003 and 13 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-23-06 has been entered.

### *Election/Restrictions*

2. It is noted that Applicants elected **without** traverse the species of minisheet of Figure 7D, the species of attachment of Figure 4D, the species of individual packaging of Figure 27 and the species of multiple packaging of Figure 23C in the reply filed on 6-8-05.

3. Claims 6-7 and 9 are still withdrawn and now also claims 1-5, 8 and 10-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6-8-05.

Applicant's remarks have been considered but claims 6 and 7, as well as claims 1-5 and 8-17 as now amended do not read on Figure 23C because each of the independent claims 1, 8, 16 and 17 require an over-wrapping film which is shown in the nonelected species of 24C not the elected species set forth supra. Note withdrawn claim 9.

***Specification***

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

For example:

***Substitute Specification***

5. The substitute specification filed 8-23-06 has not been entered because the marked up copy still does not comply with 37 CFR 1.121, i.e. does not show all the changes made to the originally filed specification to arrive at the clean copy of the substitute specification. For example, the marked up copy does not show the all the changes made to the section and subsection titles, see, e.g. page 25, last subsection title in the marked up copy and compare to original. The preliminary amendment to the description of Figure 4 is not properly reflected in the substitute specification, i.e. the marked up copy shows the changes already made by the preliminary amendment, i.e. underlining and bracketing. Therefore the following action is based on the originally filed specification including the abstract and the preliminary amendments thereto.

***Drawings***

6. The drawings were received on 12-13-05. These drawings are not approved. See the preceding paragraph with regard to Figure 27.

7. The drawings are objected to because the descriptive text in Figure 28 should be avoided. Figure 27B does not show the finger opening and the package 150 opening pointing in the same direction as described on page 50. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### *Description*

8. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: the abstract, line 5.

9. The abstract of the disclosure is objected to because terminology which can be inferred, e.g. "The present invention relates to", and legal terminology, i.e. "comprises", should be avoided. Correction is required. See MPEP § 608.01(b).

10. The disclosure is objected to because of the following informalities: 1) As set forth in MPEP 608.01(o), the meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import. The use of a confusing variety of terms for the same thing should not be permitted. The claims refer to, e.g., an exterior container comprising a package. However, a confusing variety of terms appears to have been used to describe such claim terms, e.g. the exterior container has also been referred to as the "outer vessel" in the title. Each of the claimed features should be referred to consistently by a single term rather than a variety of terms. 2) The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims are not commensurate in scope. See MPEP 608.01(d). 3) On page 18, line 8, "19a" should be after "opening" not "finger". 4) In Figure 13, what is 48? 50 in Figure 14? 70 in Figure 17? 5) How does the exterior container disinfect as set forth on page 28, lines 11-12? 6) On page 29, line 14, "12" should be --112-- and on line 15, after "film", --118-- should be inserted. 7) On page 30, lines 3 and 4, "131" should be --133--.

Appropriate correction is required.

### ***Claim Objections***

11. Claims 21-22 are objected to because of the following informalities: Claim 21 is still considered a claim depending from claim 19 but the preamble thereof is inconsistent with that of

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claim 19. Also lines 6 et seq, i.e. “an individually...pad.”, are redundant, see lines 1-2 of claim 21, i.e. “the ...claim 19”. The last line of claim 22 is grammatically incorret. Appropriate correction is required.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

12. Claims 18-22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 21, is claim 21 claiming the wrapping body within the main body, i.e. line 5, or not, i.e. lines 1-2 and line 6? For the reasons set forth infra, claims 18-22 are indefinite, vague and too broad, see Ex parte Slob, infra.

13. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 22 now claims the pad includes a treatment to reduce the number of live microorganisms and further including “sterilized by ethylene oxide gas” [sic]. While the application as original filed, e.g. page 4, line 15-page 6, line 7, describe a processing or treatment to reduce the number of live organisms which may include one or a combination of disinfection processing, e.g. sterilization using ethylene oxide gas, aseptic condition manufacturing or use of an antimicrobial agent, this is not what is claimed, i.e. the sterilization by gas is not claimed necessarily claimed as part of the treatment to reduce the number of live microorganisms to a

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certain amount. If Applicant maintains such claim language, the portion of the originally filed specification which supports the full scope of the combination claimed in claim 22 in a single embodiment should be set forth.

### ***Claim Language Interpretation***

14. With respect to all the claims, the claimed processing or treatment is not claimed as being performed at a particular time, i.e. the processing can take place any time from the beginning point of manufacture, e.g. up to time of use. Due to the lack of clarity discussed supra, claim 21 which depends from claim 19 is considered to require at a minimum an exterior container comprising a package capable of the function on lines 1-2 and 6 et seq of claim 21. It is also noted that added language of claim 20, an independent claim, also only requires the capability of containment as set forth. As set forth in 2163.06, I., claim 22 is considered to require the processing or treatments as set forth on the last three lines, i.e. some reducing treatment and sterilization treatment by gas.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

15. Claims 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in MPEP 2164.04, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. While the



analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written rejection. The language should focus on those factors reasons and evidence that lead the examiner to conclude the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

First, what is the claimed invention? As set forth in the independent claims 18, 19, 20 and 22, the invention is considered to comprise at least an interlabial pad, claims 18-19 and 22, or the capability of comprising an interlabial pad, claim 20. The interlabial pad is further claimed as being treated/including a treatment or processed to contain not more than a certain number of live microorganisms therein, due to the processing or treatment, at a point in time at least six months, i.e. at six months or longer, from the processing or treatment. See Claim Language Interpretation section supra. It is disclosed that such number is to be determined by testing. Therefore, the claims also define the invention by any tests used to determine the number of live organism rather than set forth the specific structure of the end product, i.e. the claims are test characteristic claims. The claims are also product by process claims, see discussion infra.

Second, since the physical characteristics, i.e. the number of live microorganism therein, of the labial pad must be determined, e.g., by a test used to measure such characteristic, the scope of the claims is enabled to the extent the test, i.e. the method and equipment or parameters thereof, measuring such characteristic is described or disclosed.

In the instant application, no test whatsoever, i.e. no method, no equipment, has been disclosed with regard to measurement of the claimed characteristic. Contrary to Applicant's remarks, the test described on page 49, line 12-page 52, fourth to last line, as best understood, is used to measure the number of live microorganism in 10g of pad, note page 49, lines 24-25 and compare to page 52, line 10, up to six months from processing or treating of the combination of the pad, an individual wrapping container, an exterior container and an overwrapping film not a test for the measurement of the number of live microorganism in a pad at least six months from processing or treatment of the pad alone, i.e. the claimed characteristic. Furthermore, even the description of the test which has been set forth is unclear. For example, page 4, lines 19-24 and the abstract describe the characteristic as a measurement with respect to manufacture while page 44, line 21-page 45, line 3, as well as the test on pages 49-52, describe the characteristic as a measurement with regard to the process or treatment. For another example, the disclosure of such test on pages 49-52 is unclear, i.e. page 51, lines 15-16 refer to "the above-described test" but no test is described thereabove. For a third example, page 51, lines 17-26 disclose preparing some test solution, exposing a piece of pad thereto and making some kind of observation and judgement but it is not disclosed when this happens with respect to the processing or treatment of the pad nor what is observed and judged. Similarly, page 51, last line-page 52, fourth to last line describes the testing of a certain weight of the pad but does not, e.g., describe how such weight relates to that of an entire pad, i.e. are the results of the test correlated in some manner? In other words, the tests used, especially with respect to measurement of the claimed physical characteristics, are not described or disclosed, i.e. enabled, and thus, the claims relying on such are not enabled.

Third, the claims set forth the physical characteristics desired of the pad alone rather than the specific composition of the pad in the end product. Therefore, relying on Ex parte Slob, 157 USPQ 172, such claims could cover any conceivable combination of materials whether presently existing or which might be discovered in the future and which would impart the desired characteristic, i.e. the claims are too broad and indefinite since purport to cover everything having the characteristics regardless of its composition (It should be noted that 35 USC 101 sets forth "Whoever invents or discovers any new and useful...composition of matter...may obtain a patent therefor...title, i.e. does not included compositions that have yet to be invented and discovered.)

For these reasons and evidence, the examiner concludes the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

16. Claims 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth in MPEP 2163, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not described with sufficient particularity such that one skilled in the art would recognize that the Applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in

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the specification and which is not conventional in the art to or known to one of ordinary skill in the art. Further, as set forth in *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, the lack of adequate written description also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. As discussed in the preceding rejection, the tests which are essential or critical to the selection of the pad have not been disclosed, there is a lack of disclosure or claiming of any specific composition/structure of the pad, and the claims are too broad in that the claims cover any conceivable combination of structure/processes either presently existing or which may be discovered in the future and which may impart the desired characteristics. Therefore, the claimed invention as a whole is not adequately described because the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art to or known to one of ordinary skill in the art and the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. Therefore, one skilled in the art would recognize that the Applicant did not have possession of the claimed invention.

***Claim Rejections - 35 USC § 102***

17.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

18. Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Brisebois '095.

The claim requires a package comprising a container main body and a container lid capable of packaging at least one individual wrapping, see Claim Language Interpretation section supra. See, for example, Brisebois et al at col. 1, lines 26-42 and Figures 1-2, i.e. '095 teaches a package which includes a main body, i.e. the lower portion of 102, and lid or flap, i.e. the portion of 102 shown by dashed lines, which lid/flap is continuous with the main body but bent towards and bonded to the main body to form the package. Claim 20 further requires the package having the capabilities, functions or properties set forth on lines 4 et seq, i.e. the capability of containing at least one individually wrapped body including a treated pad and a wrapping. While Brisebois '095 does not explicitly teach the package capable of containing a pad as claimed, it not only teaches the structure of claim 20 but also teaches a package capable of containing an individually wrapped body including a pad and a wrapper which covers and encloses the pad, see, e.g., col. 5, lines 25-27. Therefore, there is sufficient factual evidence for one to conclude that such same structure of '095 would also inherently include the capabilities, properties or functions claimed in claim 20.

***Claim Rejections - 35 USC § 102/103***

19. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

20. Claims 18-19 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McFall et al, PCT '689.

See Claim Language Interpretation section supra, Figures 1-5 and 8-9, and page 5, lines 19-27, page 7, first full paragraph, page 7, last full paragraph and page 33, second full paragraph,

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i.e. the pad is 20, the wrapping is 50, the permeable sheet is 42, the backsheet is 38 and the absorber is 44. The sheets each have an edge which edges are bonded to each other. The McFall reference does not explicitly teach the range of microorganisms, i.e. a test characteristic, as set forth in the last subsection of claim 18, and the second to last subsection of claims 19 and 22. However McFall does teach a processing for the suppression of the number of microorganisms sometime during and/or after the manufacture of the pad but prior to combination with the package 50, see page 29, second full paragraph. Therefore, it is the Examiner's first position that since McFall includes all the claimed structure, processing and capabilities and also expresses the desire for microorganism suppression, that there is reasonable factual basis to conclude that the structure of the McFall also inherently possesses the claimed test characteristic i.e. the claimed range of microorganism in the pad at least six months from processing or treatment thereof, when tested according to Applicant's test, as best understood, see discussion supra. In any case, note again that McFall also recognizes the same problem/solution, i.e. need for microorganism suppression, i.e. see portions of McFall cited supra. Therefore, the Examiner's second position, even if the McFall et al reference does not teach the exact range of live microorganism, the general conditions of the claim are disclosed thereby and it is not inventive, i.e. it would be obvious to one of ordinary skill in the art, to discover the optimum or workable ranges, i.e. Applicant's ranges, by routine experimentation, *In re Aller*, 105 USPQ 233 (CCPA 1955). Finally, the Examiner's third position, claims 18-19 and 22 are also product by process claims due to the language in the last sections of claims 18 and 22 and the second to last subsections of claims 19 and 22. As set forth in MPEP 2113, even though product by process claims are limited by and defined by the process, determination of novelty and inventive step is

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based on the end product itself not on its method of production. If the product in the product by process claim is the same as or obvious from the product of the prior art, the claim is unpatentable even though the prior product was made by another process. As discussed supra, since the composition of the pad of the end product is unknown, at most, the end product of the claims 1-3 is known to be a pad or/and container. Since such a product appears to be the same or similar to that of McFall et al, the claims are considered unpatentable.

21.. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over McFall in view of Brisebois et al.

The claims require an exterior container and the specifics thereof which container is capable of packaging at least one body as claimed in claim 19, see Claim Language Interpretation section supra. McFall does not teach such an exterior container. However, it is well known to package a plurality of individual wrapping body systems together in a cardboard box or other container for efficient consumer sale. See, for example, Brisebois et al at col. 1, lines 26-42. It is also well known that such boxes or other containers include a main body and lid or flap which lid or flap is continuous with the main body but bent towards and bonded to the main body to form the package, see, for example, Figures 1 and 2 of Brisebois. Therefore, to employ an exterior container having the structure claimed in claim 21 capable of packaging at individual wrapping body as taught by McFall would have been obvious to one of ordinary skill in the art in view of the recognition that such a container is well known in combination with such systems for efficient consumer sales thereof and the desire of efficient consumer sales with respect to any system intended for sale such as that taught by McFall. In so doing the prior art

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combination necessarily and inevitably teaches a package system having the capabilities, functions or properties as set forth on lines 6 et seq.

### ***Response to Arguments***

22. Applicant's remarks with regard to the matters of form have been considered but are either deemed moot in that they have not been reraised or are deemed not persuasive for the reasons set forth supra. Applicant's remarks with regard to the 112 first paragraph rejections have been considered but are deemed not persuasive for the reasons set forth supra, i.e. the test and parameters measured by the cited paragraphs are not those claimed, e.g. those measured are on some 10g of pad up to six months from processing, not measurements of a pad at least six months. With regard to the remarks with respect to the prior art Applicant's remarks are deemed narrower than the claims, the prior art teachings and the rejections based thereon, i.e. no argument has not provided which shows that the McFall does not inherently include such organism ranges, which shows it would not be obvious to include such ranges or which shows that the end product of the claims and the McFall device are different. It is noted that the claims are not method claims, they are apparatus claims. It is again noted that the claims of the elected species in this RCE application do not include the structure, e.g. an over-wrapping film, argued by Applicant as distinguishing the claims over the prior art.




*Conclusion*

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Karin M. Reichle  
Primary Examiner  
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KMR  
October 31, 2006